Knowledge Acquisition Session Report
NCI –Cancer Centers Branch
and Clinical Grants and Contracts Branch

Session Date: April 12. 2000 **Time:** 1:30-3:00 p.m.

Session Topic: Information Requirements in the Cancer Centers Branch and the Clinical Grants and Contracts Branch

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Organization: NCI Cancer Centers Branch; NCI Clinical Grants and Contracts Branch

Type of Session:

X Interview _____ Task Analysis _____ Scenario Analysis
____ Concept Analysis _____ Observation _____ Structured Interview
____ Other:

Documentation: KA Session Report
NCI-Designated Cancer Centers (P30)
Part III: Interim Formatting Instructions for New and Competing Continuation CCSG Applications
Attachment: Instructions and Formats, Standard Cancer Center Information Summaries
Clinical Grants and Contracts Branch Internal Database Fields:

- Current (table) Database Fields
- Pending (table) Database Fields
- Tumor Types (table)

Clinical Grants and Contracts Branch Grants Application Information Form
Screen Shot of Accrual System Data Entry Interface designed by CTIS

General Topic Area

Clinical grant management information requirements of the NCI Clinical Grants and Contracts Branch and the NCI Cancer Centers Branch.

Session Objectives

- Document the clinical grant management information requirements that may not be met by currently available applications for two NCI Branches: 1) Clinical Grants and Contracts Branch, and 2) Cancer Centers Branch.

Report Summary

This report summarizes information technology needs expressed by domain experts from two NCI areas: (1) the CCB (Cancer Centers Branch) and the (2) CGCB (Clinical Grants and Contracts Branch) of CTEP (Cancer Therapy Evaluation Program). CCB personnel manage NCI cancer research infrastructure grants awarded to research institutions. PAMO (Program Analysis and Management Office) recently became CGCB. CGCB personnel administer investigator-initiated clinical grants and cooperative agreements. CGCB personnel also provide scientific, technical, and administrative assistance to staff in other CTEP branches. Grants provide the majority of NCI's funding for cancer research. NCI employs many types and sizes of grants. CCB and CGCB domain experts expressed the need for information technology enhancements in three areas: (1) integration of currently unconnected information, (2) enhanced reporting capabilities, and (3) Protocol Authorization and Tracking System support for selected contract-funded CTEP studies.

Cancer Centers Branch

The Cancer Centers Branch (CCB) personnel manage cancer research infrastructure grants to major academic and research centers. Infrastructure grants involve training, technology, and other research elements that enable centers to pursue state-of-the-art cancer research efforts. When NCI awards a P30 Cancer Center Support Grant (CCSG) to an institution, the institution becomes an NCI-designated Cancer Center. Margaret Holmes leads the CCB as Branch Chief.

Clinical Grants and Contracts Branch

The Clinical Grants and Contracts Branch (CGCB) personnel administer investigator-initiated clinical grants and cooperative agreements for the Cancer Therapy Evaluation Program (CTEP). CGCB personnel handle clinical trials portfolio tracking requirements for all CTEP branches. CGCB personnel also interact scientifically, technically, and administratively with staff in other CTEP branches in the management of cooperative agreements and contracts. CTEP recently moved CGCB to branch status, and it formerly was the Protocol Analysis and Management Office (PAMO). The Branch Chief for CGCB has not yet been designated.

Funding Mechanisms

The National Cancer Institute (NCI) funds cancer research through several mechanisms. The Clinical Grants and Contracts Branch (CGCB) and Cancer Centers Branch (CCB) deal mainly with three types of funding mechanisms: grants, contracts, and cooperative agreements.

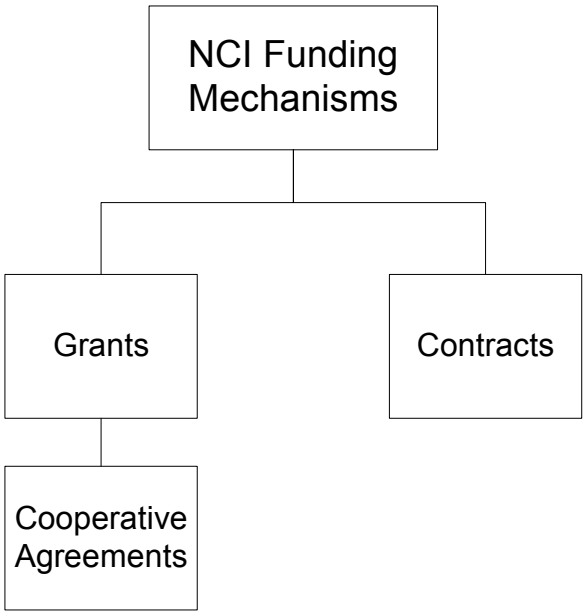

Figure 1: NCI Mechanisms for Funding Cancer Research

Grants

Grants serve as the NCI's primary method of funding cancer research. The NCI awards monetary grants to cancer centers and/or investigators to facilitate cancer research in areas of concern to the NCI. The NCI awards many different types of grants. Grant types most pertinent to CGCB and CCB activities are displayed in Figure 2.

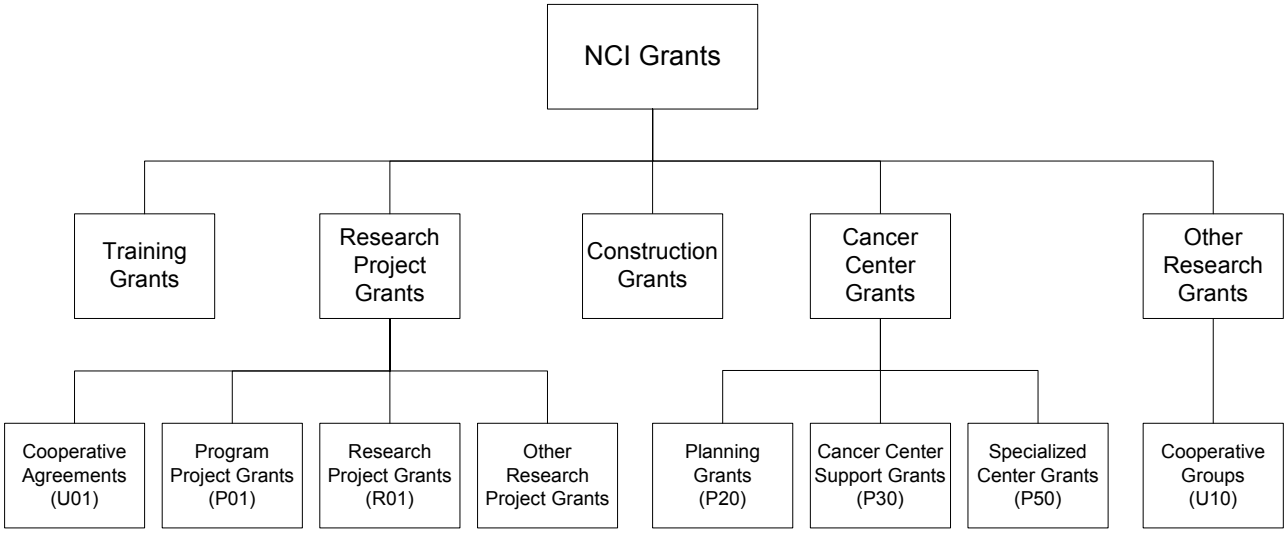

Figure 2: Types of NCI Grants

The NCI maintains various grant review bodies that evaluate grant applications and then approve or disapprove the grants. CGCB and CCB personnel deal with assistance mechanisms like grants and cooperative agreements more often than they deal with other funding mechanisms.

Training Grants

Training grants provide long-term support for a wide range of promising scientists and research clinicians. Individuals may apply for some of these grants, while other grants are geared towards the needs of institutions.

Research Project Grants

NCI supports investigator-initiated research projects by awarding Research Project Grants or Cooperative Agreements.

Cooperative Agreements (U01)

Cooperative Agreements support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing their specific interest and competencies. NCI uses this mechanism when it anticipates substantial involvement between the NCI and the recipient.

Program Project Grants (P01)

Program Project Grants support large, multi-project research efforts involving a principal investigator and multiple independent investigators. All of the projects relate directly to a central research focus and support a well-defined research goal. The size of these grants frequently exceeds $500,000.

Research Project Grants (R01)

Research Project Grants support a discrete, specified research project to be performed by the named investigator in an area representing his/her specific interest and competencies. This is generally referred to as a traditional research project.

Other Research Project Grants

Other Research Project Grants include a wide variety of grants focused on specific research issues, including Small Research Grants (R03), Exploratory/Developmental Grants (R21), Small Business Technology Transfer Grants (R41-R44), and Cooperative Agreements (U01).

Construction Grants

Construction grants support the creation of additional state-of-the-art cancer research laboratories and clinics for both basic and applied cancer research. NCI will match up to 50 percent of the allowable construction costs.

Cancer Center Grants

Cancer Centers Grants support the development of the institutions in which cancer research is performed.

Planning Grants (P20)

Planning Grants support planning for new programs, expansion or modification of existing resources, or feasibility studies for new approaches. Planning awards have assisted in the development of cancer centers and Specialized Programs of Research Excellence (SPORES).

Cancer Center Support Grants (CCSG) (P30)

CCSGs provide support primarily for the research infrastructure of an active and unified cancer center. NCI designed these grants to help cancer centers:

- consolidate and focus cancer-related activities,
- increase research productivity,
- promote shared use of research resources and improved quality control,
- stimulate and promote interdisciplinary and collaborative research, and
- increase the rate at which research discoveries are translated into medical benefits.

Cancer centers that are awarded CCSGs achieve NCI-designated Cancer Center status.

Specialized Center Grants (P50)

Specialized Center Grants support any part of the full range of research and development from very basic to clinical activities. The spectrum of activities comprises a multidisciplinary attack on cancer. These grants differ from Program Project Grants in that they are usually developed in response to an announcement of the programmatic needs of the NCI and later receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes.

Other Research Grants - Cooperative Groups

The NCI will also award cooperative agreements to fund research of specific interest to the NCI. NCI has established the Cooperative Group Program. This program encourages cancer research centers to work together to conduct large-scale clinical trials across multiple institutions. The NCI currently works with nine Cooperative Groups:

1. Cancer and Acute Leukemia Group B (CALGB)
2. Children's Oncology Group (COG)
   - ♦ formerly four different groups:
     - o Children's Cancer Study Group (CCSG)
     - o Pediatric Oncology Group (POG)
     - o Intergroup Rhabdomyosarcoma Study Group (IRSG)
     - o National Wilms' Tumor Study Group (NWTSG)
3. Eastern Cooperative Oncology Group (ECOG)
4. Gynecologic Oncology Group (GOG)
5. National Surgical Adjuvant Breast and Bowel Project (NSABP)
6. North Central Cancer Treatment Group (NCCTG)
7. Radiation Therapy Oncology Group (RTOG)
8. Southwest Oncology Group (SWOG)
9. American College of Surgeons Oncology Group (ACOSOG)

Each cooperative group maintains operations offices and staff, but research and treatment occurs at the participating institutions. Cooperative groups can accrue the large numbers of patients required for large-scale clinical trials. Cooperative group funding also spawns new clinical research studies across multiple institutions. The Division of Cancer treatment and Diagnosis controls the budget for the Cooperative Group Program. The program directors in CGCB and CCB personnel interact with grants more frequently than with cooperative group awards. Ms. Carpenter interacts more frequently with cooperative group awards than with grants.

Contracts

The NCI will frequently award contracts for the completion of research that is of specific interest to the NCI. Cancer centers and/or investigators compete for the contracts. Various evaluation bodies within the NCI review contract proposals and award the contracts. CGCB's division (the Division of Cancer Treatment and Diagnosis) plans to begin funding selected phase I and phase II studies by contract, beginning November 2000. CCB personnel do not work with contracts.

Sources of Data

Domain experts from the Clinical Grants and Contracts Branch and the Cancer Centers Branch mentioned several data sources that contain information about grants, contracts, and/or cooperative groups. Figure 3 lists those data sources and indicates the funding mechanism(s) related to each data source.

Source of Data	Grants/Cooperative Agreements	Contracts
IMPAC 1	Yes	Yes
IMPAC 2	Yes	No
IMPAC 2 Extensions	Yes	No
Clinical Data Update System	Yes	Yes
PATS	Yes	Yes
Clinical Trials Monitoring Service (ACES®)	No	Yes
Population Tracking Database	Yes	Yes
NCI EZ Accrual System	Yes	Yes
CCB Internal Database	Yes (CCB only)	No
CGCB Internal Database	Yes	No

Figure 3: Sources of Data for Funding Mechanisms

CGCB and CCB personnel may rely on sources of data beyond those listed in Figure 3. Additional KA is required to identify additional sources of data. The following is a brief description of the data sources.

IMPAC 1

The National Institute of Health (NIH) established the old IMPAC 1 system as a repository for grant-related and contract-related information throughout NIH. CGCB and CCB personnel still use the IMPAC 1 system and find that it meets some of their specific needs. For example, IMPAC 1 can produce reports in the format preferred by CGCB personnel.

IMPAC 2

NIH plans to replace IMPAC 1 with IMPAC 2. However, IMPAC 2 does not contain contract-related data. Work has been underway on IMPAC 2 for about five years.

IMPAC 2 Extensions

NIH designed IMPAC 2 to serve the needs of all the organizations within NIH. As a result, IMPAC 2 did not meet some of the requirements specific to the National Cancer Institute (NCI). The IMPAC 2 Extensions allow NCI to store information specific to NCI needs and to associate with information in IMPAC 2. NIH users who access IMPAC 2 itself can access very little of the IMPAC 2 Extensions information.

Clinical Data Update System (CDUS)

The CDUS system supports the collection and reporting of clinical trial information. It includes information such as patient accruals and toxicity results. CDUS reports this information quarterly.

Protocol Authorization and Tracking System (PATS)

The PATS system supports the creation, review, approval, and tracking of clinical trial protocols using NCI-sponsored investigational agents. It includes information such as review dates, investigator contact information, and planned patient accruals. In some cases CTEP enters protocols into PATS when grant numbers have not yet been assigned. No mechanism currently exists for entering the grant numbers later in PATS. This causes difficulty in reporting protocol information by funding mechanisms. However, planned PATS enhancements include the ability to update grant numbers.

Clinical Trials Monitoring Service (CTMS)

CTMS' ACES® data management system collects clinical trial information such as patient accruals for selected phase I and phase II studies. It contains information that cannot be found in CDUS, and it is updated once every two weeks. In the near future, CDUS will be updated so that CTMS information is loaded into it monthly. Theradex, a contract research organization, maintains the CTMS system.

NIH Population Tracking Database (PTDB)

The NIH Population Tracking Database connects to IMPAC 1 and contains patient accrual information broken down by gender and ethnicity by protocol. CGCB personnel enter grant-related accrual information into the PTDB via an application called EZ Accrual. The CDUS system also provides PTDB cooperative group-related accrual information, although that process is not automated.

EZ Accrual

LGA, Inc. created the EZ Accrual system. The system provides a mechanism to enter patient accrual data and pass it on the PTDB. CGCB personnel enter accrual information for over 700 protocols using EZ Accrual. EZ Accrual includes some information not found in PTDB. This includes protocol name, protocol phase, and type of clinical trial (therapeutic versus other). EZ Accrual allows CGCB personnel to see miscoded grants immediately and pursue correction without waiting for year end reporting. However, it does not meet CGCB's ad-hoc reporting needs as well as the MS Access database system that it replaced.

CCB Internal Database

Cancer Centers Branch personnel maintain an internal database for tracking information relevant to its programs. For each center, CCB personnel collect lists of protocol names, protocol phases, target accruals, accruals to date, accruals in past twelve months, and new patient information (by cancer site and by type of protocol). The centers update this information annually.

CCB personnel collect information on the following types of clinical trials:

- Peer review funded trials (such as P01 grants)
- Cooperative group trials
- Trials developed and funded by research institutions
- Trials developed and funded by industry

CCB personnel find it difficult to collect information on the latter two types of trials because reporting to NCI is voluntary.

CGCB Internal Database

CGCB maintains an internal MS Access database to track CTEP grants and cooperative agreements. CGCB personnel use this database to produce ad-hoc reports as well as standard reports for program directors.

The CGCB Internal Database consists of three tables:

- Current (data kept on active grants)
- Pending (data kept on pending grants)
- Tumor Type (data on tumor type and location, linked to both other tables)

These tables are populated by manual data entry of information from grant applications and award notices.

Prior to the implementation of EZ Accrual, CGCB personnel entered patient accrual information into an MS Access database. This database was linked to the CGCB Internal Database, and CGCB personnel used it to produce ad hoc accrual reports. Although EZ Accrual does not meet this need as well, CGCB personnel cannot afford to enter data in both systems. The MS Access accrual database is no longer updated.

Ms. Carpenter also maintains a separate Excel file to track information about Cooperative Groups. Ms. Carpenter uses this file to create budget projections.
This file tracks the following information about Cooperative Group awards:

- Authorized awards
- Actual awards
- Carry over from year to year

Information Technology Requirements

The domain experts expressed the need for information technology assistance in three main areas:

1. Integrating currently unconnected information
2. Enhanced reporting capabilities
3. Protocol Authorization and Tracking System support for selected contract-funded CTEP studies

The Cancer Centers Branch (CCB) and Clinical Grants and Contracts Branch (CGCB) domain experts did not express the same information technology needs in each area. The figure below shows which information technology requirements apply to each of the branches.

Requirement Area/Requirement	CCB	CGCB
1. Integrating Currently Unconnected Information		
Linking Grants, Subject Areas, Dollars, Budget Components, and Accrual Data		Applies
Identifying Protocols in the CTEP Review Process		Applies
Access to CTMS Data		Applies
Consolidate the Cancer Center Data Submission	Applies	
Snapshot of All Clinical Trials		Applies
Data Coding and Integration	Applies	Applies
2. Enhanced Reporting Capabilities		
Reporting Grant Information at Any Time	Applies	Applies
Sorting Report Information	Applies	Applies
Annual Accruals		Applies
Ad hoc Reporting for Accruals		Applies
3. Protocol Authorization and Tracking System support for selected contract-funded CTEP studies		Applies

Figure 4: Information Technology Requirements

The following is a brief description of each information technology requirement.

Integrating Currently Unconnected Information

Linking Grants, Subject Areas, Dollars, and Budget Components

Clinical Grants and Contracts Branch (CGCB) personnel need a system that links grants, the grants' subject areas, the amount of money awarded in each grant, and grant budget information. Ann Carpenter mentioned IMPAC 2 and the Extramural Financial Database (EFDB) as two sources of budget information.

Identifying Protocols in the CTEP Review Process

CGCB personnel sometimes receive grant applications in which protocols are mentioned. They would like the capability to identify whether the protocol is also currently in the CTEP protocol review process.

Access to CTMS Data

CGCB personnel use the Clinical Data Update System (CDUS) to update the Population Tracking Database (PTDB) in cases where principal investigators fail to report accruals. However, some studies' accruals are tracked through the Clinical Trials Monitoring System (CTMS) rather than CDUS. CGCB personnel would like access to CTMS information as well as CDUS information. Lisa Chatterjee noted that in the near future CTMS data will be loaded into CDUS monthly.

Consolidate the Cancer Center Data Submission

Margaret Holmes pointed out that Cancer Centers frequently report the same information to different NCI bodies in slightly different formats. For example, Cancer Centers Branch, Cancer

Therapy Evaluation Program, and Physicians Desk Query all require cancer centers to report similar clinical trial data. Dr. Holmes felt that this process might be consolidated or simplified.

Snapshot of All Clinical Trials

Ms. Carpenter noted that if NCI wanted a snapshot of all clinical trials, there is no single data source that could provide this information. She felt that an NCI clinical trials database is needed to resolve this problem.

Data Coding and Integration

CGCB personnel sometimes respond to questions about clinical trials, but their research is complicated by a lack of effective coding and system integration. For example, CGCG received a Congressional request about gene therapy trials. CGCB personnel worked many evenings and relied heavily on their memories to complete the request. Ms. Carpenter felt that the required information existed in various NCI databases, but the coding and integration required to pull it together did not exist.

Cancer Centers Branch (CCB) personnel also require coding that links grant information to IMPAC 2 data. For supplemental initiatives, they want to know the funding status and the relationship to any larger parent grant.

Dr. Holmes pointed out that Barbara Lamb in the Grants Operations Section is already performing a certain amount of coding when grants arrive in her section. Dr. Holmes suggested that Ms. Lamb's process might be a model for resolving some of the coding issues.

Enhanced Reporting Capabilities

Reporting Grant Information at Any Time

CGCB personnel need to be able to report grant status and details at any time. Ms. Carpenter felt that this capability was critically important to people who control budgets. Ms. Carpenter referred to the FY Access System as an example of the type of system that would meet this need. Steve Hughes of the NCI Office of Informatics developed the FY Access system. Mr. Hughes and Lisa Chatterjee said that a new tool called Discoverer would meet the need expressed by Ms. Carpenter. Rollout and training for Discoverer is scheduled to be complete by May 31, 2000.

Sorting Report Information

CGCB personnel need to sort report information by sub-activity code. Ms. Carpenter and Ms. LoMonico were uncertain how the sub-activity codes are being assigned. At one time CGCB personnel assigned the codes using a paper pay list. Now that the paper pay list has been automated it is unclear how sub-activity codes are assigned and updated.

CCB personnel would like to sort report information by the following elements:

- Subprogram
- Kind of trial (therapeutic, correlative, ancillary, prevention, population sciences)

- Cancer site
- Institution

Annual Accruals

CGCB personnel cannot currently track clinical trial accruals within the past year. CDUS and grant progress reports provide total accruals, but not the number of accruals within the past twelve months. CGCB personnel could ask the Grants Administration Branch (GAB) for this information on a grant by grant basis, but that would be extremely time consuming. Ms. Carpenter said that acquiring annual accruals is primarily a grantee reporting challenge. However, CGCB would require a mechanism for storing annual accrual data in the event that it is collected from grantees.

Ad Hoc Reporting for Accruals

CGCB personnel would like the ability to produce ad hoc reports on accruals. The MS Access database used by CGCB prior to EZ Accrual provided this capability. Ms. Carpenter felt that EZ Accrual provides useful functionality, but accrual reporting capabilities need to be enhanced.

Protocol Authorization and Tracking System support for selected contract-funded CTEP studies

The Division of Cancer Treatment and Diagnosis (DCTD) will soon begin funding selected phase I and phase II early therapeutic clinical trials by contract. DCTD plans to award the first of these contracts in November 2000. The Protocol Authorization and Tracking System (PATS) will need to support tracking of clinical trials funded by contracts.

Entries for Domain Dictionary

IMPAC 1: The grants accounting system used by NIH. It contains information that is used by NCI program directors.

IMPAC 2: A new grants accounting system planned for NIH. It has been under development since approximately 1995. It will replace IMPAC 1.

IMPAC 2 Extensions: Additions to the IMPAC 2 system that are designed to meet NCI-specific needs.

EZ Accrual: A computer system created by LGA, used to enter accrual information for transmission to the Population Tracking Database.

FY Access System: A computer system designed by the NCI Office of Informatics, used to run reports on data in the IMPAC 1 system.

DEA: Division of Extramural Activities

CCB: Cancer Centers Branch

CGCB: Clinical Grants and Contracts Branch; formerly Program Analysis Management Office (PAMO).

CTMS: Clinical Trials Monitoring Service; this service uses ACES ®, a system that captures data once every two weeks for selected phase I and phase II clinical trials.

Program Director: A scientist working for NCI who manages a portfolio of grants and cooperative agreements in a science area.

Theradex: A clinical trials monitoring contract organization that specializes in clinical oncology trials. This organization holds manages the Clinical Trials Monitoring System. Theradex's website is www.theradex.com.